UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,440	09/19/2003	Timothy John Henkel	9404.0005-02	8311

22852 7590 06/04/2004

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,440	HENKEL, TIMOTHY JOHN	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 09/19/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Information Disclosure Statement dated 09/19/03.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 4 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The term "acute" in claims 4 and 11 is a relative term, which renders the claim indefinite. The term "acute" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claim is unclear as to the appropriate dosage size of an acute dosage, and therefore is indefinite. Applicant can overcome this rejection by amending or canceling the claim.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 7-12, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al (WO 98/42705). The claims are drawn to a method of treating chronic bronchitis, a respiratory infection, by administering an antibacterial agent gemifloxacin and/or salt and

derivative thereof. Kim discloses all of the derivatives and salts thereof (mesylate and sesquihydrate), and teaches that the compound can be used to treat respiratory infections. The reference provides a method of administration of the compound also (Abstract; page 10, line 6 – page 11 line 3.) These disclosures along with others leave these claims anticipated.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-14 rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (WO 98/42705) in view of Sherlock (USPN 4452800) and knowledge in the art. The claims are drawn to a method of treating chronic bronchitis comprising administering gemifloxacin and some of its salts. As discussed Kim discloses the compound used in the method of the claimed invention, along with its appropriate salts and derivatives. The reference teaches the use of this compound, along with its salts and derivatives as useful in the treatment of respiratory diseases. The

reference does not teach the specific dosage amounts as recited by applicant in claims 6 and 15. The reference discloses a general administration of the compound of up to 400 mg, for a time to be determined by one of ordinary skill in the art. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller,* 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s), and administration durations. However, the preparations of various pharmaceutical preparations having various amounts of the active, administered on various durations, is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *In re Russell,* 439 F.2d 1228, 169 USPQ 426 (CCPA 1971).

It is known in the art to use 1,8-naphthyridine compounds in the treatment of respiratory diseases such as bronchitis and pulmonary obstruction such as asthma. Sherlock teaches that 1,8-naphthyridine derivatives are useful, in *in vitro* testing for the treatment of bronchitis and other chronic obstruction disorders such as asthma (column 1, line 65 – column 2, line 10). Also as seen at the 39th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy, gemifloxacin is known in the art to be useful in the treatment of respiratory infections, including various respiratory infections. C. L. Clark et al, A. Ogasawara et al, L. M. Ednie et al, T.A. Davies et al, V. Berrie et al and P. M. Robin et al, all presented their results from their studies of gemifloxacin and its response to various influenza strains, namely *Haemophilus influenzae* and *Streptococcus pneumonia.* Each poster disclosed the conclusion that gemifloxacin was useful in

the treatment of respiratory tract infections caused by *H influenzae* and *S pneumonia*, which are the pathogen associated with acute exacerbation of chronic bronchitis. With this knowledge one of ordinary skill in the art would have been motivated to use the compound of Kim to treat chronic respiratory and pulmonary disorders due to its anti-bacterial and anti-allergenic properties. It would have been obvious to one of ordinary skill in the art, at the time of the invention to use the teachings of Kim along with the knowledge in the art of Sherlock, with the expected result of a treatment regime successful in treating chronic pulmonary and respiratory diseases.

5. Claims 1, 4 – 6, 8 and 11 – 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowe et al (Drugs, vol.59, no.5, pgs. 1137 – 1147) in view of Grossman (Chest, vol. 112, no. 6, suppl. 310s – 313s). These claims are drawn to methods of treating the recurrence and severity of recurrence of AECB in a patient comprising administering gemifloxacin. Claims 4 and 11 recite that an acute dosage is administered. Claims 5 and 12 recite that the treatment method is an elective treatment. Claims 6 and 13 recite the specific dosage regimen.

Lowe discloses the effectiveness of gemifloxacin against *H influenzae* and *Moraxella catarrahalis* and other respiratory pathogens (Abstract). Lowe also discloses the usual dosage as 320 mg/day used in clinical trials (Abstract). Though Lowe does not disclose a specific method of treatment for AECB it does provide a method for fighting the pathogens, which are associated with the disorder. Also the length of the administration of a pharmaceutical can be and is determined by one of ordinary skill in the art. With this in mind, these disclosures render the claims 1, 6, 8 and 13 obvious. Claims 4 and 11 recite that an acute dosage is administered; yet this "acute" dosage amount is not defined by the claim. As discussed above the "acute"

language renders the claims indefinite, therefore rendering the claims 4 and 11 obvious in view of the dosage provided by Lowe. Claims 5 and 12 recite that the treatment is elective. Though not explicitly disclosed by Lowe, the treatment of pathogens, specifically those that are associated with AECB is common in the art. As seen in Grossman, infections of *H. influenzae* are treated with antibiotics and beta-lactam agents (312s, para. 1, 2). These treatments are best treated with antibiotics and would be in the best interest of the patient. These disclosures render the claims obvious. One of ordinary skill in the art would have been motivated by the teachings of Grossman and Lowe to treat a case of AECB with the recommended dosage of gemifloxacin. A skilled artisan would have followed the teachings of Grossman, that the pathogen associated with the disorder are treated with beta-lactam agents and other antibiotics, and applied the knowledge of Lowe that gemifloxacin is effective against said pathogens. It would have been obvious to one of ordinary skill in the art, at the time of the invention to follow the teachings in this way with an expected result of a method of treatment of AECB involving the administration of gemifloxacin.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 3rd European Congress of Chemotherapy Poster Book (May, 2000) discloses several poster presentations teaching the effectiveness of gemifloxacin against influenza infections in the respiratory tract. Cormican et al (Antimicrobial Agents and Chemotherapy, vol. 41, no. 1) teaches the antimicrobial activity of a novel fluronaphthyridone compound. Davies et al (Antimicrobial Agents and Chemotherapy, vol. 44, no. 2) teaches the antipneumococcal

activities of gemifloxacin. Heaton et al (Antimicrobial Agents and Chemotherapy, vol. 43, no. 12) teaches the activity of gemifloxacin against penicillin and ciprofloxacin resistant *S pneumoniae*.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1615

MP Young

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600